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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,115	04/04/2001	Gwong-Jen J. Chang	14114.0332U3	4134

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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,115

Applicant(s)

CHANG, GWONG-JEN J.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07232003</u> . | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 09/826,115
Applicant: Chang, G.-J.

Docket No.: 14114.0332U3
Filing Date: 04/04/01

Detailed Office Action

Status of the Claims

Applicants' election of Group I (claims 1-17 and 28-37) in the response filed 30 September, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)).

Information Disclosure Statement

The information disclosure statement filed 14 April, 2003, fails to comply with 37 C.F.R. § 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has **not** been considered.

The supplemental information disclosure statement filed 23 July, 2003, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 103(a)

1. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

2. Claims 1-17 and 28-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yasui *et al.* (1990) in view of Kochel *et al.* (2002) and Ivy *et al.* (2000).

Yasui and colleagues describe the preparation of recombinant baculovirus and vaccinia virus expression vectors encoding the prM, E, and NS1 proteins of the Japanese encephalitis virus (JEV). Expression cassettes were prepared comprising signal sequences and the respective genes under the control of various promoters. The authors reported (see Abstract, p. 663) that **"PrM and E proteins which had predictable signal sequences upstream on the N terminals were expressed with antigenically active form and molecular size the same as the authentic ones by the recombinant viruses.** However, the recombinant viruses which had no such signal sequence expressed unprocessed proteins with antigenically denatured forms. These results suggest that normal proteolytic processing is needed to construct biologically active structures of JEV structural proteins." This teaching does not disclose constructs encoding a signal sequence from a first flavivirus and a second flavivirus immunogen.

Kochel and associates describe the preparation of nucleic acid dengue virus vaccines comprising a nucleic acid encoding the prM signal sequence and the envelope protein. These genes may be from the same isolate or different isolates. This teaching does not disclose the utilization of a JEV prM signal

sequence or signal and antigen sequences from non-DEN coding regions.

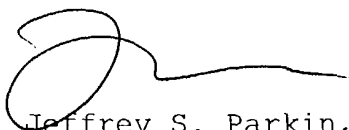
Ivy and colleagues describe the preparation of nucleic acid constructs comprising a first nucleotide sequence encoding a signal sequence and a second nucleotide sequence encoding the E antigen of any given flavivirus (e.g., dengue, JEV, TBE, YFV, WNV, or SEV). The signal sequence may consist of either the htPA_L leader sequence or the prM leader sequence.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare an expression cassette encoding the prM signal sequence and a flavivirus immunogen (e.g., Env) as taught by Yasui et al. (1990), and to substitute immunogenic sequences from other flaviviruses, as suggested by Kochel et al. (2002) and Ivy et al. (2000), since this expression cassette would provide a facile means for inducing immune responses against the flavivirus of interest.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

21 February, 2004